Claims

- 1. A method for the treatment or prophylaxis of a retroviral infection comprising administering to a subject a poxvirus vector encoding an antigen of the retrovirus or the retrovirus antigen and a cytokine, or a functional homolog, derivative, part or analog of the retrovirus antigen and/or the cytokine, in conjunction with anti-retroviral drug therapy wherein the antigen or the antigen and the cytokine are expressed in the subject and are effective in maintaining or prolonging a low retroviral load in the subject for a period of time and are effective in preventing, reducing or delaying viral rebound during interruption of anti-retroviral drug treatment.
- 2. The method of claim 1, wherein the retroviral infection is HIV infection.
- 3. The method of claim 1 or 2, wherein the vector is administered to a subject exhibiting a low retroviral viral load as a result of anti-retroviral drug therapy.
- 4. The method of claim 1 or 2, wherein the vector is administered to a subject exhibiting a low retroviral load prior to commencement of anti-retroviral drug therapy.
- 5. The method of claim 1, 2, 3 or 4, wherein the cytokine is selected from IFNγ, IL-12, IL-2, TNF and IL-6.
- 6. The method of claim 5, wherein the cytokine is IFNy.
- 7. The method of any one of claims 1 to 6, wherein the retrovirus antigen is encoded by a coding region selected from gag, env, pol and pro coding regions.
- 8. The method of claim 7, wherein the retrovirus antigen is encoded by gag and/or pol coding regions.

- 9. The method of claim 8, wherein the retrovirus antigen is encoded by gag and pol coding regions of HIV.
- 10. The method of any one of claims 1 to 9, wherein the poxvirus vector is an avipox virus vector.
- 11. The method of claim 10, wherein the avipox virus vector is a fowlpox virus vector.
- 12. A method for the treatment or prophylaxis of HIV/AIDS comprising administering to a subject a poxvirus vector comprising a sequence of nucleotides encoding a retrovirus antigen and a sequence of nucleotides encoding a cytokine, or a functional homolog, part, derivative or analog of the antigen and/or the cytokine, in conjunction with anti-retroviral drug therapy, wherein said method is effective in maintaining a low retroviral load in the subject and preventing, reducing or delaying retroviral rebound in the absence of anti-retroviral drug therapy.
- 13. The method of claim 12, wherein the retrovirus antigen is an HIV antigen.
- 14. The method of claim 12 or 13, wherein the vector is administered to a subject exhibiting a low retroviral viral load as a result of anti-retroviral drug therapy.
- 15. The method of claim 12 or 13, wherein the vector is administered to a subject exhibiting a low retroviral load prior to commencement of anti-retroviral drug therapy.
- 16. The method of claim 12, 13, 14 or 15, wherein the cytokine is selected from IFNγ, IL-12, IL-2, TNF and IL-6.
- 17. The method of claim 16, wherein the cytokine is IFNy.

- 18. The method of claim 17, wherein IFNγ comprises the amino acid sequence set forth in SEQ ID NO: 6 or an amino acid sequence having at least about 60% similarity thereto.
- 19. The method of claim 17, wherein IFNγ is encoded by a sequence of nucleotides set forth in SEQ ID NO: 5 or a sequence of nucleotides encoding a functional homolog, part, derivative or analog thereof having at least 60% similarity thereto, or a sequence which hybridises thereto or to a complementary form thereof under conditions of medium stringency.
- 20. The method of any one of claims 12 to 19, wherein the retrovirus antigen is encoded by a coding region selected from gag, env, pol and pro coding regions.
- 21. The method of claim 20, wherein the retrovirus antigen is encoded by gag and/or pol coding regions.
- 22. The method of claim 21, wherein the retrovirus antigen is encoded by gag and pol coding regions of HIV.
- 23. The method of claim 22, wherein the retrovirus antigens encoded by gag and pol comprise the amino acid sequence set forth in SEQ ID NO: 2 or a functional homolog, part or derivative thereof or a sequence of amino acids having at least 60% similarity thereto, and SEQ ID NO: 4 or a functional homolog, part or derivative thereof, or a sequence of amino acids having at least 60% similarity thereto, respectively.
- 24. The method of claim 22, wherein the retrovirus antigen encoded by gag is encoded by a sequence of nucleotides set forth in SEQ ID NO: 1 or a sequence of nucleotides encoding a functional homolog, part or derivative thereof having at least 60% similarity thereto after optimal alignment or a sequence which hybridises thereto or to a complementary form thereof under conditions of medium stringency,

and wherein the retrovirus antigen encoded by pol is encoded by a sequence of nucleotides set forth in SEQ ID NO: 3 or a sequence of nucleotides encoding a functional homolog, part or derivative thereof having at least 60% similarity thereto after optimal alignment or a sequence which hybridises thereto or to a complementary form thereof under conditions of medium stringency.

- 25. The method of any one of claims 12 to 24, wherein the poxvirus vector is an avipox virus vector.
- 26. The method of claim 25, wherein the avipox virus vector is a fowlpox virus vector.
- 27. The method of claim 26, wherein the insertion site in the fowlpox vector comprises the sequence of nucleotides set forth in SEQ ID NO: 7.
- 28. A method of reducing or alleviating one or more side effects of anti-retroviral drug therapy comprising administering to a subject exhibiting a retroviral infection a poxvirus vector comprising a sequence of nucleotides encoding an antigen of the retrovirus or a functional derivative, homolog, part or analog thereof, and a sequence of nucleotides encoding a cytokine or a functional derivative, homolog, part or analog thereof, for a time and under conditions sufficient to co-express the antigen and the cytokine and to reduce or alleviate one or more side effects of anti-retroviral drug therapy in the subject.
- 29. The method of claim 28, wherein the retroviral infection is HIV infection.
- 30. The method of claim 28 or 29, wherein the vector is administered to a subject exhibiting a low retroviral viral load as a result of anti-retroviral drug therapy.
- 31. The method of claim 28 or 29, wherein the vector is administered to a subject exhibiting a low retroviral load prior to commencement of anti-retroviral drug therapy.

- 32. The method of claim 28, 29, 30 or 31, wherein the cytokine is selected from IFNγ, IL-12, IL-2, TNF and IL-6.
- 33. The method of claim 32, wherein the cytokine is IFNy.
- 34. The method of claim 33, wherein the IFNy comprises the amino acid sequence set forth in SEQ ID NO: 6 or an amino acid sequence having at least about 60% similarity thereto.
- 35. The method of claim 33, wherein IFNy is encoded by a sequence of nucleotides set forth in SEQ ID NO: 5 or a sequence of nucleotides encoding a functional homolog or derivative thereof having at least 60% similarity thereto, or a sequence which hybridises thereto or to a complementary form thereof under conditions of medium stringency.
- 36. The method of any one of claims 28 to 35, wherein the retrovirus antigen is encoded by a coding region selected from gag, env, pol and pro coding regions.
- 37. The method of claim 36, wherein the retrovirus antigen is encoded by gag and/or pol coding regions.
- 38. The method of claim 37, wherein the retrovirus antigen is encoded by gag and pol coding regions of HIV.
- 39. The method of claim 38, wherein the retrovirus antigens encoded by gag and pol comprise the amino acid sequence set forth in SEQ ID NO: 2 or a functional homolog, part or derivative thereof, or a sequence of amino acids having at least 60% similarity thereto, and SEQ ID NO: 4 or a functional homolog, part or derivative thereof, or a sequence of amino acids having at least 60% similarity thereto, respectively.

- 40. The method of claim 38, wherein the retrovirus antigen encoded by gag is encoded by a sequence of nucleotides set forth in SEQ ID NO: 1 or a sequence of nucleotides encoding a functional homolog, part or derivative thereof, having at least 60% similarity thereto after optimal alignment, or a sequence which hybridises thereto or to a complementary form thereof under conditions of medium stringency, and wherein the retrovirus antigen encoded by pol is encoded by a sequence of nucleotides set forth in SEQ ID NO: 3 or a sequence of nucleotides encoding a functional homolog, part or derivative thereof having at least 60% similarity thereto after optimal alignment, or a sequence which hybridises thereto or to a complementary form thereof under conditions of medium stringency.
- 41. The method of any one of claims 28 to 40, wherein the poxvirus vector is an avipox virus vector.
- 42. The method of claim 41, wherein the avipox virus vector is a fowlpox virus vector.
- 43. The method of claim 42, wherein the insertion site in the fowlpox vector comprises the sequence of nucleotides set forth in SEQ ID NO: 7.
- 44. A use of a recombinant vector comprising a sequence of nucleotides encoding a retrovirus antigen or a functional derivative, homolog, part or analog thereof, and a sequence of nucleotides encoding a cytokine or a functional derivative, homolog, part or analog thereof in the manufacture of a medicament for use in maintaining or prolonging a low retroviral load in a subject for a period of time, and in preventing, reducing or delaying viral rebound during interruption of anti-retroviral drug treatment.
- 45. A use of a recombinant vector comprising a sequence of nucleotides encoding a retrovirus antigen or a functional derivative, homolog, part or analog thereof, and a sequence of nucleotides encoding a cytokine or a functional derivative, homolog,

part or analog thereof, in the manufacture of a medicament for use in reducing or alleviating one or more side effects of anti-retroviral drug therapy.

- 46. A use according to claim 44 or 45, wherein the retrovirus is HIV.
- 47. A recombinant poxvirus vector comprising a sequence of nucleotides encoding a retrovirus antigen or a functional homolog, derivative, part or analog thereof, and a sequence of nucleotides encoding a cytokine or a functional homolog, derivative, part or analog thereof, for use in conjunction with anti-retroviral drug therapy to maintain or prolong a low retroviral load in a subject and to prevent, reduce or delay viral rebound during interruption of anti-retroviral drug treatment in a subject.
- 48. A recombinant poxvirus vector comprising a sequence of nucleotides encoding a retrovirus antigen or a functional homolog, derivative, part or analog thereof, and a sequence of nucleotides encoding a cytokine or a functional homolog, derivative, part or analog thereof, for use in reducing or alleviating one or more side effects of anti-retroviral drug therapy.
- 49. The recombinant poxvirus vector of claim 48, wherein the for use in maintaining or prolonging a low retroviral load in the subject and reducing or alleviating one or more side effects of anti-retroviral drug therapy.
- 50. The recombinant poxvirus vector of claims 47, 48 or 49, wherein the retrovirus is HIV.
- 51. The recombinant vector of claims 47, 48, 49 or 50, wherein the cytokine is selected from IFNy, IL-12, IL-2, TNF and IL-6.
- 52. The recombinant vector of claim 51, wherein the cytokine is IFNy.

- 53. The recombinant vector of claim 52, wherein the IFNγ comprises the amino acid sequence set forth in SEQ ID NO: 6 or an amino acid sequence having at least about 60% similarity thereto.
- 54. The recombinant vector of claim 52, wherein IFNγ is encoded by a sequence of nucleotides set forth in SEQ ID NO: 5 or a sequence of nucleotides encoding a functional homolog or derivative thereof having at least 60% similarity thereto or a sequence which hybridises thereto or to a complementary form thereof under conditions of medium stringency.
- 55. The recombinant vector of any one of claims 47 to 54, wherein the retrovirus antigen is encoded by a coding region selected from gag, env, pol and pro coding regions.
- 56. The recombinant vector of claim 55, wherein the retrovirus antigen is encoded by gag and/or pol coding regions.
- 57. The recombinant vector of claim 56, wherein the retrovirus antigen is encoded by gag and pol coding regions of HIV.
- 58. The recombinant vector of claim 57, wherein the retrovirus antigens encoded by gag and pol comprise the amino acid sequence set forth in SEQ ID NO: 2 or a functional homolog, part or derivative thereof or a sequence of amino acids having at least 60% similarity thereto, and SEQ ID NO: 4 or a functional homolog, part or derivative thereof or a sequence of amino acids having at least 60% similarity thereto, respectively.
- 59. The recombinant vector of claim 57, wherein the retrovirus antigen encoded by gag is encoded by a sequence of nucleotides set forth in SEQ ID NO: 1 or a sequence of nucleotides encoding a functional homolog, part or derivative thereof having at least 60% similarity thereto after optimal alignment or a sequence which hybridises

thereto or to a complementary form thereof under conditions of medium stringency, and wherein the retrovirus antigen encoded by *pol* is encoded by a sequence of nucleotides set forth in SEQ ID NO: 3 or a sequence of nucleotides encoding a functional homolog, part or derivative thereof having at least 60% similarity thereto after optimal alignment or a sequence which hybridises thereto or to a complementary form thereof under conditions of medium stringency.

- 60. The recombinant vector of any one of claims 47 to 59, wherein the poxvirus vector is an avipox virus vector.
- 61. The recombinant vector of claim 60, wherein the avipox virus vector is a fowlpox virus vector.
- 62. The recombinant vector of claim 61, wherein the insertion site in the fowlpox vector comprises the sequence of nucleotides set forth in SEQ ID NO: 7.